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| 09/851,606      | 05/08/2001  | Rubinah K. Chowdhary | 273012011700        | 4962             |

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EXAMINER

KISHORE, GOLLAMUDI S

ART UNIT PAPER NUMBER

1615

DATE MAILED: 08/19/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/851,606

Applicant(s)

Chowdhary

Examiner

Gollamudi Kishore

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE three MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-30 is/are pending in the application.
- 4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-30 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some\* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 7 6) ☐ Other:

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## **DETAILED ACTION**

### ***Claim Rejections - 35 USC § 112***

- 1. The following is a quotation of the first paragraph of 35 U.S.C. 112:**

**The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.**

- 2. Claims 1-30 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for compositions containing endosupports, does not reasonably provide enablement for exo-support. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. A careful review of the specification (page 41) indicates that applicant defines exo-support as any support that partially or wholly coats or encloses or encapsulates the medicament and carrier mixtures. However, applicant neither defines these supports in terms of specific compounds nor provides an example to show how one what the nature of the compounds is and how the components are incorporated. This is essential since according to the invention, the carrier forms liposomes upon contact with water. There is no description in the specification how the carrier which is further encapsulated within the exo-support would come into contact with water and form liposomes where the liposomes are formed (within the exo-support or in the host system). Broad claims must have broad basis of support in the specification; in**

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the absence of such support, claims must be limited to compositions containing endo-supports which applicant describes as useful in practicing the invention. One of ordinary skill in the art will not be able practice the invention without undue experimentation.

**3.The following is a quotation of the second paragraph of 35 U.S.C. 112:**

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

**4. Claims 3, 12, 15, 21-25 and 27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.**

According to claim 1, the mixture upon hydration leads to the formation of liposomes; claims 3 and 27 which recites micelles and others thus, is inconsistent with claim 1. Similar is the case with claims reciting block copolymers (20-25). Clarification is requested since these do not form liposomes.

It is unclear whether the limitations in parenthesis are indeed the limitations as recited in claims 12 and 24-25.

The examiner suggests reciting the chemical names instead of abbreviations for compounds in claims 15, 24 and 25.

It is unclear as to how the endosupport is removed after hydration as recited in claim 18. This is essential since the claim is a method of preparation claim.

‘type’ in claim 21 is indefinite; see Ex parte Copenhaver, 109 USPQ 118.

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***Claim Rejections - 35 USC § 102***

**5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:**

**A person shall be entitled to a patent unless -**

**(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.**

**6. Claims 1-16, 19 and 26-30 are rejected under 35 U.S.C. 102(b) as being anticipated by Madden (5,389,378).**

**Madden discloses lyophilized powders containing a phospholipid, a benzoporphyrin and lactose (endosupport) for photodynamic therapy (note Examples). The formulations are enclosed in a capsule (exo-support).**

**(e) the invention was described in-**

**(1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or**

**(2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).**

**7. Claims 1-17, and 26-30 are rejected under 35 U.S.C. 102(e) as being anticipated by Desai (6,074,666).**

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**Desai discloses lyophilized powders containing a phospholipid, a benzoporphyrin and lactose (endosupport) for photodynamic therapy (note columns 6-7, Examples and claims, claim 8 in particular).**

***Claim Rejections - 35 USC § 103***

**8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:**

**(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.**

**9. Claims 1-20 and 27-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over either Lentini (5,885,557) or Young (6,375,930) in further combination with Unger (6,028,066).**

**Lentini, and Young both disclose that photodynamic therapy could be practiced with photosensitizing material in carriers such as micelles and liposomes (note the abstract, col. 7, line 62 through col. 8, line 29 of Lentini; abstract, col. 11, line 33 through col. 13, line 43).**

**What is lacking in Lentini and Young is the teachings of the inclusion of a saccharide such as trehalose and polymers such as PEG and polyvinyl pyrrolidone and freeze-dry the composition to a solid state.**

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Unger while disclosing the formulations containing liposomes and micelles for therapeutic and diagnostic purposes teaches that lyophilized compositions have advantage of greater shelf life and to prevent the agglutination as a result of lyophilization, additives such as glucose and trehalose are added (note the abstract, col. 4, lines 9-58 and col. 79, lines 45-57).

To include sugars such as trehalose and lyophilize the preparations of Lentini or Young would have been obvious to one of ordinary skill in the art because Unger teaches that lyophilized compositions have advantage of greater shelf life and to prevent the agglutination as a result of lyophilization, additives such as glucose and trehalose and polymers such as PEG and polyvinyl pyrrolidone are added.

10. Claims 21-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over either Lentini (5,885,557) or Young (6,375,930) in further combination with Unger (6,028,066) as set forth above, further in view of Kataoka (Journal of controlled Medicine, 1993) of record.

The teachings of Lentini, Young and Unger have been discussed above. What is lacking in these references is the teaching of the use of instant block polymers.

Kataoka teaches that using polyoxyethylene-polyoxypropylene block polymers for the preparation of micelles and subsequent use for drug delivery have advantages such as high carrying capacity for the hydrophobic drugs, simple sterilization by micro filtration and prolonged storage in a freeze-dried state (note the abstract and Table 1).

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**The use of the block polymers as the material in the preparation of micelles of Lentini, Young and Unger would have been obvious to one of ordinary skill in the art because of the advantages of these polymers as taught by Kataoka.**

**11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to *G.S. Kishore* whose telephone number is (703) 308-2440.**

**The examiner can normally be reached on Monday-Thursday from 6:30 A.M. to 4:00 P.M. The examiner can also be reached on alternate Fridays.**

**If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, T.K. Page, can be reached on (703)308-2927. The fax phone number for this Group is (703)305-3592.**

**Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [thurman.page@uspto.gov].**



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**All Internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark on February 25, 1997 at 1195 OG 89.**

**Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703)308-1235.**



**Gollamudi S. Kishore, Ph. D**

**Primary Examiner**

**Group 1600**

*gsk*

**August 12, 2002**